

REMARKS

Claims 1-24 are pending. Claims 1-10, 12-15 and 20-23 have been withdrawn.

Claim 11 has been amended to require that the starting material is a hyaluronic acid with an average molecular weight of 150,000 to 730,000 Daltons. Support for this amendment can be found in the Specification on page 19, line 19. The claim has also been amended to require that the crosslinked derivative has a degree of crosslinking of 4.5 to 5% and a viscosity of greater than $200 \text{ Pa} \cdot \text{sec}^{-1}$. Support for these amendments can be found in original claim 16 and in the Specification on page 19, lines 29-30.

Claim 16 has been amended to require a viscosity of at least $250 \text{ Pa} \cdot \text{sec}^{-1}$. Support for this amendment can be found in the Specification on page 19, lines 30-32.

Claim 19 has been amended to recite a gel as one of the biomaterials. Support for this amendment can be found in original claim 10.

Claim 20 has been amended to depend from claim 11.

Claim 21 has been amended to correct the dependency from claim 20.

No new matter has been added.

Amendment of Claims 20 and 21

Applicant has amended claims 20 and 21, which were withdrawn as being directed to a biomaterial, to depend from claim 11. Applicants note that claims 20 and 21 were merely withdrawn and not canceled and so are pending. Consequently, the amendment to claims 20 and 21 do not increase the number of pending claims. Neither do they require a new search as they

are dependent on claim 11. Thus, Applicants respectfully request entry of the amendments to claims 20 and 21.

Rejections Under 35 USC § 103

Della Valle in view of Malson

The Examiner has rejected claims 11, 16, 19 and 24 as obvious over Della Valle et al (EP 341745) in view of Malson et al (US 5,783,691). The Examiner contends that Della Valle teaches the application of an autocrosslinked derivative of hyaluronic acid to tissues involved in surgery. The Examiner contends that Malson teaches that crosslinked hyaluronic acid derivatives are known generally to be useful in medical applications, such as prevention of surgical adhesions. The Examiner concludes that it would have been obvious for the skilled artisan to use the Della Valle products for the prevention of post-surgical adhesions and that one would have a reasonable expectation of success in so doing. Applicants respectfully traverse.

The Examiner states that Malson teaches that HA and crosslinked HA derivatives are known generally to be useful in medical applications. But this does not mean that all HA derivatives and crosslinked derivatives are useful for each and every purpose. This concept is exemplified in Study 8 beginning on page 52 of the Specification.

Study 8 compares the efficacy of five (5) different batches (A-E) of 5% autocrosslinked hyaluronic acid (“ACP”) that differ only in the viscosity associated with each batch. As can be seen from Tables 4 and 5 (page 56), not all 5% ACP gels produced the same results. Only those with a viscosity higher than 200 Pa*sec⁻¹ (see page 52) were effective in significantly reducing

the numbers of adhesions. In fact, when the viscosity was below $200 \text{ Pa} \cdot \text{sec}^{-1}$, the percentage of adhesions were greater than untreated controls.

The Della Valle reference, while disclosing autocrosslinked hyaluronic acid derivatives, provides no guidance as to the degree of viscosity that is necessary to achieve fewer adhesions than the untreated controls. In fact, the Della Valle does not even contain the term “viscosity.” The void in discussing viscosity is not filled by the Malson reference, which likewise does not address the need for highly viscous derivatives.

Thus, the combination of the Della Valle reference and the Malson reference do not teach the instant invention or suggest that viscosity is a critical feature of the invention. Consequently, Applicants respectfully request reconsideration and removal of the rejection.

Della Valle in view of Malson and Matsuda

The Examiner has rejected claims 11, 16, 19 and 20 as obvious over Della Valle in combination with Malson and Matsuda (US 5,462,976). The Della Valle and Malson references are discussed above. The Examiner acknowledges that these references do not teach the range of forms listed in claim 19.

With respect to Matsuda, the Examiner contends that this reference also teaches that glycosaminoglycans, such as HA, are useful for the prevention of surgical adhesions as well as teaching that these crosslinked biopolymers may be prepared in a variety of forms.

The Examiner contends that it would have been obvious to the skilled artisan to prepare the Della Valle crosslinked HA material in any form known to be used for surgical applications with a reasonable expectation of success. Applicants respectfully traverse.

As discussed above, **not all** crosslinked HA derivatives are useful for each and every purpose. Consequently, even considering the combined teachings with the Matsuda reference, which does not mention viscosity at all, use of the instant invention for prevention of post-surgical adhesions is not obvious as none of the references teach the importance of a viscosity of at least $200 \text{ Pa} \cdot \text{sec}^{-1}$.

In view of the above, Applicants respectfully request reconsideration and removal of the rejection.

Della Valle in view of Malson and Leshchiner

The Examiner has rejected claims 11, 16, 19 and 24 as obvious over Della Valle in combination with Malson and Leshchiner (US 5,399,351). The Della Valle and Malson references are discussed above. The Examiner acknowledges that these references do not teach any specific type of surgery.

Regarding Leshchiner, the Examiner contends the reference teaches that viscoelastic gels comprising crosslinked biopolymers, such as HA derivatives, have utility for prevention of post-operative adhesions.

The Examiner contends that it would have been obvious to the skilled artisan to prepare the Della Valle crosslinked HA material in any form known to be used for surgical applications with a reasonable expectation of success. Applicants respectfully traverse.

As discussed above, **not all** HA derivatives and crosslinked derivatives are useful for each and every purpose. Consequently, even considering the combined teachings with

Leshchiner, use of the instant invention for prevention of post-surgical adhesions is not obvious as none of the references teach the importance of a viscosity of at least $200 \text{ Pa} \cdot \text{sec}^{-1}$.

In view of the above, Applicants respectfully request reconsideration and removal of the rejection.

Della Valle in view of Malson and Dorigatti

The Examiner has rejected claims 11, 16, 19 and 24 as obvious over Della Valle in combination with Malson and Dorigatti (WO 94/17837). The Della Valle and Malson references are discussed above. The Examiner acknowledges that these references do not teach the use of a biomaterial comprising a non-biodegradable synthetic polymer.

The Examiner contends that Dorigatti teaches the use of a HA derivative in combination with various synthetic polymers and that this material has utility as an anti-adhesive product for use in surgery.

The Examiner contends that it would have been obvious to the skilled artisan to modify the Dorigatti product by use of the Della Valle crosslinked HA material and to use it for prevention of surgical adhesions with a reasonable expectation of success. Applicants respectfully traverse.

As discussed above, **not all** HA derivatives and crosslinked derivatives are useful for each and every purpose. Consequently, even considering the combined teachings with Dorigatti, use of the instant invention for prevention of post-surgical adhesions is not obvious as none of the references teach the importance of a viscosity of at least $200 \text{ Pa} \cdot \text{sec}^{-1}$.

Thus, Applicants respectfully request reconsideration and removal of the rejection.

Application No. 10/812,587
Amendment dated February 28, 2007
Reply to Office Action of September 29, 2006

Docket No.: 2039-0124PUS2

Accordingly, in view of the above amendments and remarks, reconsideration of the rejections and allowance of the claims of the present application are respectfully requested. In the event that the Amendment does not place the present application into condition for allowance, entry thereof is respectfully requested as placing the present application into better condition for appeal.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Susan W. Gorman (Reg. No. 47,604) in Costa Mesa, CA at telephone number 858-792-8855 to conduct an Interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

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Respectfully submitted,

By 

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